

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

September 5, 2007
TXR # 0054708

SUBJECT: RED-0350-26839: Denatonium benzoate

PC Code: 009106
DP Barcode: D340819, D340820

FROM: Gregory Akerman, Ph.D. *Greg Akerman 9/5/07*
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THROUGH: Jess Rowland, Chief *Jess Rowland 9/5/07*
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I. CONCLUSIONS

The genetic toxicity studies (MRID 47146901, 47146902) for Denatonium benzoate (Bitrex) are unacceptable.

II. ACTION REQUESTED

To review genetic toxicity studies (MRID 47146901 and 47146902) for Denatonium benzoate.

*Rec'd in RRC
2007
SH*

III. BACKGROUND

Johnson Matthey Macfarian Smith has submitted genetic toxicity studies to support the registration of its technical, Denatonium benzoate (Bitrex) for use as a feeding depressant/repellent.

IV. RESULTS/DISCUSSION

MRID 47146901 Bitrex Technical Report on the Microbial Mutagenicity Screen on Denatonium Benzoate.

This study has both technical issues and protocol deficiencies. In the Ames assay, the background plate counts (spontaneous revertants) for both TA98 and TA100 tester strains are lower than values typically seen in this assay¹. Low background counts may indicate plasmid loss in these strains. The guideline deficiencies are listed below:

- No purity information for the technical provided
- No Quality Assurance statement provided
- GLP statement states the that the submitter does not know whether the study was conducted in accordance with 40 CFR Part 160
- No certificate of analysis provided
- No Materials and Methods information provided. The report simply states that the tests were conducted according to the following departmental standard operation procedures:

SOP/WGT/0002/01: Minimum inhibitory concentration (MIC)

SOP/WGT/0022/01: Ames test

SOP/WGT/0025/01: Yeast gene conversion assay

SOP/WGT/0026/02: Fluctuation test

- No information on the preparation of the S9-mix (only reference to SOP/WGT/0034/01 provided)
- No information on negative control/solvent used

MRID 747146902- Micronucleus Test with Bitrex (Denatonium Benzoate)

While the study appears to be technically sound, there are numerous protocol deficiencies that prevent this study from being classified as an acceptable guideline study. The major deficiencies are listed below:

- No purity information for the technical provided

¹ de Serres FJ, Shelby MD, Recommendations on Data Production and Analysis Using the Salmonella/Microsome Mutagenicity Assay. Environ Mut 1:87-192, 1979.

- No Quality Assurance statement provided
- GLP statement states the that the submitter does not know whether the study was conducted in accordance with 40 CFR Part 160
- No certificate of analysis provided

Version date: 1/18/07